

K213411 iSR'obot Mona Lisa 2.0Dec 22, 2021
64 days to decisionK213411 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k213411/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Oct 19, 2021
Decision date	Dec 22, 2021
Days to decision	64 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Biobot Surgical Pte., Ltd.
Location	Alexandria, VA, US
Contact	Lim Yan Shin
510(k) history	7 submissions · 7 cleared · 2011-2023

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